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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/492,213	01/27/2000	Gerard J Gundling	6416.US.P1	9588
23492 75	590 09/23/2005		EXAMINER	
ROBERT DEBERARDINE ABBOTT LABORATORIES			SISSON, BRADLEY L	
100 ABBOTT PARK ROAD		ART UNIT	PAPER NUMBER	
DEPT. 377/AP6A			1634	
ABBOTT PAR	RK, IL 60064-6008		DATE MAILED: 09/23/2005	

Please find below and/or attached an Office communication concerning this application or proceeding.

		Application No.	Applicant(s)					
Office Action Summary		09/492,213	GUNDLING ET AL.					
		Examiner	Art Unit					
	·	Bradley L. Sisson	1634					
	The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply							
WHIC - Exten after 9 - If NO - Failur Any re	DRTENED STATUTORY PERIOD FOR REPLY HEVER IS LONGER, FROM THE MAILING DASIONS of time may be available under the provisions of 37 CFR 1.13 (SIX (6) MONTHS from the mailing date of this communication. period for reply is specified above, the maximum statutory period we to reply within the set or extended period for reply will, by statute, exply received by the Office later than three months after the mailing d patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUN 36(a). In no event, however, may vill apply and will expire SIX (6) M cause the application to become	NICATION. a reply be timely filed  ONTHS from the mailing date of this con ABANDONED (35 U.S.C. § 133).					
Status				• *				
1)[\]	Responsive to communication(s) filed on 27 Ju	<u>ıne 2005</u> .						
2a)⊠	This action is <b>FINAL</b> . 2b) ☐ This	action is non-final.						
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is								
	closed in accordance with the practice under E	x parte Quayle, 1935 C	.D. 11, 453 O.G. 213.					
Dienociti	on of Claims			•				
•				:.				
4)⊠ Claim(s) <u>17-27</u> is/are pending in the application.								
	4a) Of the above claim(s) is/are withdraw	vn from consideration.		\$				
5) Claim(s) is/are allowed.								
6)⊠ Claim(s) <u>17-27</u> is/are rejected.								
7) Claim(s) is/are objected to.								
8)	Claim(s) are subject to restriction and/or	r election requirement.	•	•				
Application	on Papers			5·				
9)⊠ The specification is objected to by the Examiner.								
10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.								
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).								
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).								
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.								
Dui a uita a ca	ndon 25 H O O C 440							
•	nder 35 U.S.C. § 119			• •:				
,	Acknowledgment is made of a claim for foreign All b) Some * c) None of: 1. Certified copies of the priority documents		. § 119(a)-(d) or (f).					
	2.☐ Certified copies of the priority documents		Application No.					
	3. Copies of the certified copies of the prior		· ·	Stage				
	application from the International Bureau	u (PCT Rule 17.2(a)).						
* S	ee the attached detailed Office action for a list	of the certified copies n	ot received.					
Attachmant	(c)	•		· · · · · · · · · · · · · · · · · · ·				
Attachment	e of References Cited (PTO-892)	4) 🗀 Interview	N Summary (PTO-413)	:				
2) Notice of Draftsperson's Patent Drawing Review (PTO-948) Paper No(s)/Mail Date.								
3) Inform	3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  Paper No(s)/Mail Date  5) Notice of Informal Patent Application (PTO-152)  6) Other:							
Paper	NO(S)/IVIAII Date	6) 🔲 Otner: _	·					

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#### **DETAILED ACTION**

# Specification

1. The specification is objected to as documents have been improperly incorporated by reference. In particular, the specification states:

As all of these patents are assigned to the assignee of the present case, the disclosures of those patents are incorporated herein in their entirety.

Such omnibus language fails to specify what specific information applicant seeks to incorporate by reference and similarly fails to teach with detailed particularity just where that specific information is to be found in each of the cited documents.

2. Attention is also directed to MPEP 608.01(p)I, which, in pertinent part, is reproduced below:

Mere reference to another application, patent, or publication is not an incorporation of anything therein into the application containing such reference for the purpose of the disclosure required by 35 U.S.C. 112, first paragraph. In re de Seversky, 474 F.2d 671, 177 USPQ 144 (CCPA 1973). In addition to other requirements for an application, the referencing application should include an identification of the referenced patent, application, or publication. Particular attention should be directed to specific portions of the referenced document where the subject matter being incorporated may be found. (Emphasis added)

As set forth in Ex parte Raible, 8 USPQ2d 1707, (BPAI, 1998)

The examiner is of the opinion that the general incorporation by reference of the Bentley disclosure in appellant's specification is insufficient to support the specific disputed limitations of the present claims in the manner required by section 112 of the statute. We agree

We believe that the doctrine of incorporation by reference is of no avail to appellant inthis regard since there is no specific indication in the instant specification of the particular features disclosed by Bentley which correspond to those intended for use in the hereclaimed device; nor does the specification identify the specific portions of the patent which appellant may have intended to rely upon to supplement his disclosure. The

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purpose of incorporation by reference in an application of matter elsewhere written down is for economy, amplification, or clarity of exposition, by means of an incorporating statement clearly identifying the subject matter which is incorporated and where it is to be found. In re de Seversky, 474 F.2d 671, 177 USPQ 144, (CCPA 1973).

Accordingly, the cited documents are not considered to have been properly incorporated by reference and as such, have not been considered with any effect towards their fulfilling, either in part or in whole, the enablement, written description, or best mode requirements of 35 USC 112, first paragraph.

# Response to argument

- 3. At page 7, bridging to page 8 of the response received 27 June 2005, argument is presented that the form of he citation is proper, and that "if incorporation by reference is deemed to be inappropriate, it may be corrected by adding the incorporated disclosure by amendment (37 C.F.R. § 1.57(f))." Said representative adds further that this form of statement can be found in issued patent documents.
- 4. The above argument has been fully considered and has not been found persuasive towards the withdrawal of the objection. As an initial matter, the merits of each application are considered on a case-by-case basis. Accordingly, the aspect of applicant's representative having found like language in an issued patent does not control.
- 5. The aspect of the documents having been improperly incorporated by reference cannot be cured by amending the specification by bringing in part or parts of the various disclosures. It is because of the fact that the documents have been improperly incorporated by reference that applicant is precluded from doing this very act. Therefore, and in the absence of convincing evidence to the contrary, the objection is maintained.

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6. The amendment filed 27 June 2005 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material, which is not supported by the original disclosure, is as follows: The new title, the new abstract, and the new text added to page 3.

Applicant is required to cancel the new matter in the reply to this Office Action.

# Claim Rejections - 35 USC § 112

- 7. The following is a quotation of the first paragraph of 35 U.S.C. 112:
  - The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
- 8. Claims 17-27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The original title and all original claims of the application are directed to a method for processing a sample containing at least one biological element. Pages 2-3 of the original disclosure set forth with greater particularity the embodiments of the invention. As seen therein, the embodiments comprise 5 methods for processing a sample containing at least one biological element. None of the stipulated embodiments, none of the original claims, nor the title or abstract suggests that applicant contemplated their invention to be anything other than a method for processing a sample. These statements indicate that the invention is different from what is

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defined in the claim(s) because none of the present claims are directed to a method of processing a sample. Rather, all pending claims are directed to a device. The amendment to the specification, including the title and abstract are considered to constitute new matter.

- 9. It is well settled that "[I]t is not enough for purposes of written description requirement of Section 112 that the disclosure, when combined with the knowledge in the art, would lead one to speculate as to modification that the inventor might have envisioned, but failed to disclose."

  Lockwood v. American Airlines Inc. (Fed. Cir. March 1997) 41 USQP2d 1961 at 1966.

  Likewise, it is not enough for applicant's representative to now assert that applicant wishes to claim a device or structure when the original specification, original title, original claims and original abstract all point to the invention being a method.
- 10. For the above reasons, and in the absence of convincing evidence to the contrary, claims 17-27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

### Conclusion

- 11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).
- 12. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

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will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

- Any inquiry concerning this communication or earlier communications from the 13. examiner should be directed to Bradley L. Sisson whose telephone number is (571) 272-0751. The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.
- If attempts to reach the examiner by telephone are unsuccessful, the examiner's 14. supervisor, W. Gary Jones can be reached on (571) 272-0745. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.
- Information regarding the status of an application may be obtained from the Patent 15. Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Bradley L. Sisson Primary Examiner

Bd. Sirson

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**BLS** 

12 September 2005